

KY Hepatitis Connections

We hope you and your family enjoyed a relaxing Labor Day! Inside this September 2015 edition of the KY Hepatitis Connections you will find information about hepatitis screening, testing, and treatment, and opportunities for viral hepatitis continuing professional education. See all the exciting things happening here in hepatitis!

As always, feel free to forward, copy and/or distribute this newsletter to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on our families throughout the Commonwealth. We hope you enjoy the September newsletter.

Kathy Sanders, RN, MSN



In the News:

Hepatitis C Screening at the Kentucky State Fair:

The KY Adult Viral Hepatitis Prevention Program and University of Louisville Gastroenterology/ Liver Transplant clinic team partnered with KentuckyOne and OraSure to provide HCV education and screening to state fair attendees. More than 170 individuals were tested at no cost for HCV.



Pictured: Left: Dr. Matt Cave, Right: Barbra Cave, Kathy Sanders, Stephanie Linn, and Jack Frontczak

A Special thanks to our sponsors: KentuckyOne OraSure Pharmacy Plus



IAS 2015: Indiana HIV Outbreak -- Lessons about Containing Local Outbreaks and Harm Reduction

August 2015: The CDC issued an official health advisory about the outbreak in April, and CDC and Indiana investigators published a brief report in the May 1 edition of *Morbidity and Mortality Weekly Report*.

John Brooks, leader of the CDC's HIV Epidemiology Team, described efforts to determine the source of the Indiana outbreak, trace patterns of transmission, halt further infections, and bring affected people into care. He also presented results from a molecular epidemiology analysis of HIV and HCV strains, providing insight into how the viruses spread.

Brooks said a disease intervention specialist first recognized that 2 people newly diagnosed with HIV had shared needles for drug injection; contact tracing soon identified 8 more cases. Health officials interviewed newly diagnosed individuals, asking about their needle-sharing behaviour and injection and sex partners. People were given the opportunity to suggest any social contacts they thought "might benefit from an HIV test" without naming them as sex or dug use partners. All named individuals who could be located were offered HIV, HCV, hepatitis B virus, and syphilis testing.

Investigators identified nearly 500 individuals during contact tracing, 83% of who were located, assessed for risk, and tested for HIV. As of June 14, a total of 170 people were diagnosed with HIV. After a rapid increase in mid-March and April, the outbreak plateaued. "We could tell we were closing in on the epidemic when no contacts named were new," Brooks said.

More than half (55%) of the newly diagnosed individuals were men, all were non-Hispanic white, and the median age was 32 years (range 19-56 years). Among those who tested HIV-positive, about 40% reported needle-sharing as their only risk factor, 1% reported only sexual risk, another 40% reported both needle-sharing and sexual risk, and nearly 20% had unknown risk factors, according to the study abstract.

Almost all newly diagnosed people (96%) reported injection drug use. They described crushing, dissolving, and heating extended-release oxymorphone, and some used methamphetamine and heroin as well. The reported daily number of injections ranged from 4 to 15, and the number of injection partners ranged from 1 to 6 per injection event. Interview participants reported that injection drug use in this community is often multi-generational, and family and community members frequently inject together and share syringes and other equipment. The Indiana outbreak reflects a recent upsurge in non-urban injection drug use in the U.S. that has led to increases in HIV and HCV infection and overdose deaths.

The newly diagnosed population was rural, all white, and nearly evenly split between men and women. In contrast, prior outbreaks have traditionally involved inner-city residents, often African-American or Latino, with a 2-to-1 ratio of men to women. But other factors of the Indiana outbreak were similar, including a high rate of poverty (19%), unemployment (9%), low education level (21% without a high school diploma), and limited access to insurance and health care. Read more: <a href="http://www.hivandhepatitis.com/hiv-aids/hiv-aids-topics/hiv-prevention/279,646-hiv-injection-drug-use-hiv-injection-drug-use/5325-ias-2015-indiana-hiv-outbreak-offers-lessons-about-containing-local-



outbreaks-and-need-for-harm-reduction

Hepatitis C cure associated with significant improvement in liver stiffness in people with HIV and HCV co-infection

A successful response to hepatitis C virus (HCV) therapy is associated with a significant improvement in liver stiffness among people with HIV and HCV co-infection, French investigators report in the online edition of *AIDS*. Patients were followed for an average of 45 months, and significant regression of liver stiffness from pre-treatment levels was observed in successful responders with fibrosis and cirrhosis. Liver stiffness is considered to be a good non-invasive marker of liver fibrosis stage.

"A SVR [sustained virological response] to HCV therapy was independently associated with a decrease in liver stiffness," comment the authors. "It is noteworthy that this decrease in liver stiffness occurred not only in patients with fibrosis but also in patients with cirrhosis."

Large numbers of people living with HIV also have hepatitis C (HCV co-infection). Liver disease is now a leading cause of illness and death for people with this co-infection. Treatment is available for HCV, and its aim is sustained virological response – an undetectable HCV viral load six months after the completion of treatment. A successful response to HCV therapy has been associated with a reduction in the risk of liver disease.

But the impact of SVR on fibrosis regression is unclear. Liver stiffness can give a good indication of fibrosis stage and has the advantage of being measured by a non-invasive scan. Investigators from the French ANRS CO13 HEPAVIH cohort designed a prospective observational study to assess the impact of SVR on liver stiffness up to two years after the completion of HCV therapy.

Read More: http://www.aidsmap.com/Hepatitis-C-cure-associated-with-significant-improvement-in-liver-stiffness-in-people-with-HIV-and-HCV-co-infection/page/2990054/

One in four hepatitis C patients denied initial approval for drug treatment

Nearly one in four patients with chronic hepatitis C (HCV) are denied initial approval for a drug therapy that treats the most common strain of the infection, according to a Yale School of Medicine study.

The finding, published Aug. 27 in PLOS ONE, identifies a new barrier to caring for patients with this severe condition.

Prior to the FDA approval of novel antiviral therapies for HCV in 2014, treatment options for patients were limited, requiring weekly injections of interferon-based therapy that caused severe side effects. The new regimens revolutionized treatment and offered patients an oral therapy with cure rates exceeding 90%. However, the high cost of care led insurers to impose new restrictions on drug authorization.

Read More: http://news.yale.edu/2015/08/27/one-four-hepatitis-c-patients-denied-initial-approval-drug-treatment



Hepatitis B

Prevention of Perinatal Hepatitis B Transmission

Some infants are developing HBV infection despite being vaccinated. Which infants are at risk and what can be done to prevent HBV infection in these infants?

In the video link below, Dr. Schillie discusses the results of a study in the journal *Pediatrics* that examined outcomes of infants born to women infected with hepatitis B virus (HBV). Perinatal exposure is an important mode of HBV transmission, resulting in chronic disease in approximately 90% of infected infants. Immunoprophylaxis consisting of HBV vaccine and HBV immune globulin given within 12 hours of birth, and completion of the three-dose HBV vaccine series, are the cornerstones of perinatal HBV infection prevention. Immunoprophylaxis for infants born to hepatitis B surface antigen-positive mothers reduces up to 95% of perinatal HBV infections.

However, despite recommended immunoprophylaxis, the study showed that perinatal HBV transmission still occurs in approximately 1% of vaccinated infants born to infected mothers. Infection occurs more commonly among infants born to mothers who are younger, who are Asian/Pacific Islander, who are HBV e-antigen positive, or who have high viral loads, as well as among infants who receive fewer than three HBV vaccine doses.

Perinatal HBV transmission may be further reduced by identifying pregnant women at the greatest risk of transmitting the virus to their infants and providing these women with antiviral therapy prior to delivery. Those at most risk include mothers with high viral loads or who are HBV e-antigen positive. Preventing perinatal HBV transmission is a critical part of the national strategy to eliminate HBV infection in the United States.

It's important for healthcare providers to understand that HBV in pregnant women poses a serious risk for chronic HBV infection, liver failure, and hepatocellular carcinoma in their infants. Following national guidelines that include the universal screening of pregnant women for HBV during pregnancy, case management of mothers with HBV and their infants, provision of timely immunoprophylaxis consisting of HBV vaccine and HBV immune globulin for infants born to infected mothers, as well as routine vaccination of all infants with the HBV vaccine series with the first dose administered shortly after birth, are of paramount importance.

View the video: http://www.medscape.com/viewarticle/850040

American Liver Foundation:

Know someone who needs help with the cost of medications? The American Liver Foundation Helpline can assist. Call 1-800-GO-LIVER (1-800-465-4837).



Study shows caffeine decreases risk of hepatic fibrosis in male HCV patients

In a cross-sectional study, researchers found that coffee and caffeine were associated with a decreased risk of developing advanced hepatic fibrosis among a majority of male veterans with hepatitis C virus infection, according to study data.

Researchers, including Hashem B. El-Serag, MD, MPH, of Baylor College of Medicine and Michael E. DeBakey VA Medical Center in Houston, analyzed data of 910 veterans with chronic HCV infection and evaluated each person's daily intake of caffeinated and decaffeinated beverages, including coffee, tea and soda. The daily intakes of these beverages among the cohort were evaluated to determine any association with hepatic fibrosis through the FibroSURE test (BioPredictive, Paris, France). In addition, the researchers sought to determine the role insulin resistance played in any type of association between the drinks and fibrosis.

"Other studies have shown that insulin resistance worsens hepatic inflammation in HCV patients, and that the protective effect of coffee, at least in part, may be a consequence of coffee intake-associated reduction in insulin resistance and type 2 diabetes mellitus," the researchers wrote. "Few studies have examined the effect of coffee, as well as caffeine intake from non-coffee beverages, on the severity of liver fibrosis in patients with untreated chronic HCV infection after adjustment for insulin resistance and diabetes status."

Read More: http://www.healio.com/hepatology/hepatitis-c/news/online/%7B4e64c76e-8934-4fec-b440-3d1c8fbda095%7D/study-shows-caffeine-decreases-risk-of-hepatic-fibrosis-in-male-hcv-patients

Daktari collaborates with Merck for rapid HCV screening test

Daktari Diagnostics announced a new collaboration with Merck over the development of its rapid hepatitis C virus infection screening test, according to a press release. The test, known as the Daktari System, is based on high-sensitivity measurement of the HCV core antigen, which is currently used in Europe and Japan for diagnosing chronic HCV, but has never been available as a point-of-care diagnostic, according to the release. The test uses a point-of-care instrument that can detect low levels of HCV directly in a single drop of blood in approximately 30 minutes. This could enable clinicians to make HCV treatment decisions within the diagnostic appointment.

The new collaboration, which is worth up to \$8.5 million over the next 3.5 years, was put in place in hopes of faster development and validation processes, with regulatory approval of the product to follow, according to Daktari founder and CEO, Bill Rodriguez, MD.

Read More: http://www.healio.com/hepatology/hepatitis-c/news/online/%7Ba16de177-d010-4d3e-9106-5aaa872e926c%7D/daktari-collaborates-with-merck-for-rapid-hcv-screening-test?sc_trk=internalsearch



Interferon-free therapies improve liver function in HCV patients

Antiviral therapy without interferon improved liver function in patients with hepatitis C virus infection-related advanced cirrhosis, according to data from an observational cohort study. Researchers analyzed data of 80 patients with HCV-associated liver cirrhosis undergoing treatment with a combination of direct-acting antivirals without interferon. Of these patients, 43% had Child-Pugh B/C cirrhosis (n = 34), and 53% had platelet counts of less than $90,000/\mu$ L (n = 42). The combination regimens included Sovaldi (sofosbuvir, Gilead Sciences) with ribavirin (n = 56), Olysio (sofosbuvir/simeprevir, Janssen Therapeutics) with or without ribavirin (n = 15) and sofosbuvir and Daklinza (daclatasvir, Bristol-Myers Squibb) with or without ribavirin (n = 9). Most patients had HCV genotype 1 (n = 50), followed by 24 with genotype 3, four with HCV genotype 2 and two patients with genotype 4.

Overall, all patients became HCV RNA negative during therapy, and 63% achieved a sustained virologic response. MELD scores improved up until 12 weeks post-treatment in 44% of the patients, but worsened in 15%. Albumin, bilirubin, cholinesterase, and prothrombin time improved among all patients during therapy.

Twenty-three of the patients experienced HCV RNA relapse after completion of antiviral treatment. Ninety-one percent of patients who relapsed showed signs of detectable HCV RNA at 4 weeks post-treatment. HCV RNA relapse led to moderate ALT increases in 15 patients, but this was not associated with hepatic decompensations, according to the data.

Read More: http://www.healio.com/hepatology/hepatitis-c/news/online/%7B47dc34a6-72d3-4119-a5ed-610ec3364d61%7D/interferon-free-therapies-improve-liver-function-in-hcv-patients

Hepatitis in Corrections:

The National Hepatitis Connections Network (NHCN) in collaboration with The Center for Health Justice has produced an updated version of the handout "Hepatitis C in Prison and Jail."

This booklet is intended to be an educational resource for incarcerated people. **It is FREE to download and print** from the website.

To download: http://www.hcvinprison.org/resources/71-main-content/content/179-resources-for-health-educators

Stay tuned for a Spanish version that is in the works!





Lexington-Fayette County Health Department Syringe Exchange:

On Friday, September 4th after months of planning, the Lexington Fayette County Health Department held their first needle exchange program. The program, which allows used needles to be exchanged for clean needles, will be held on Fridays, 1:30-4:00pm at the main health department location, 650 Newtown Pike. The free, anonymous, and confidential program is designed to reduce the spread of HIV and hepatitis in Lexington.

Watch the "Lexington Fayette County Health Department Needle Exchange Walk Through" video: https://www.youtube.com/watch?feature=player_embedded&v=R3dJy5JJ-kc



Hepatitis C and Mental Health

Hepatitis C is also associated with mental health problems, particularly depression: Studies show the rate of depression is as high as 30 percent among patients.

Why? Being diagnosed with a potentially deadly disease can understandably set off mood disorders, and the disease itself may cause brain changes that affect mood. It may be that underlying mood ills lead some patients to engage in behaviors, such as IV drug use, that expose them to infection in the first place. Depression is also a well-known side effect of interferon, one of the main therapies used to treat hepatitis C.

As a result of the link to risky behaviors, people with hepatitis C often feel stigmatized by their diagnosis. "The stigma comes because injection drug use is a risk factor for hepatitis C. Many of my patients never used drugs, and others may have experimented briefly years ago. They can experience a lot of stigma and guilt. We try to help them work through it and focus on treatment. At some point, it doesn't matter how you got it -- you need to get cured and move on," says Andrew Muir, M.D., director of gastroenterology/hepatology research at Duke Clinical Research Institute in Durham, NC. That's true whether or not they can recall an event of possible exposure. "Often this hits them out of the blue," he says. "They have no idea that they're infected and find out when they go to donate blood or get life insurance, and are tested for hepatitis."

Read More: http://www.thebody.com/content/76062/hepatitis-c-and-your-mental-health.html

Training Resource: Hepatitis C Online

This is a free educational web site from the University of Washington. The site is a comprehensive resource that addresses the diagnosis, monitoring, and management of hepatitis C virus infection. This free educational series is funded through a cooperative agreement from CDC. http://www.hepatitisc.uw.edu/

Clinical Trials

<u>www.ClinicalTrials.gov</u> is a government-run clinical trial site. Type in "HCV" in the search engine, it will bring up all clinical trials. If looking for a particular drug study—type in "HCV" and "the drug name." Once you find a clinical trial—click through until you find where the clinical trial site resides—city and state.





REMINDER: HEPATITIS C Reporting:

Hepatitis C: Perinatal and Children Aged Five Years or Less

Health care providers should report, http://www.lrc.ky.gov/kar/902/002/020.htm

- all HCV-positive pregnant women;
- all infants born to HCV-positive women; and
- all HCV-positive infants and children aged 5 years old and younger seen in birthing hospitals, medical practices and clinics

Routine testing for HCV is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Data from the CDC states that approximately 6 out of every 100 infants born to HCV infected women become infected. The risk is greater, 2 to 3 times, if the woman is co-infected with HIV. There is currently no HCV treatment approved for pregnant women.

http://www.cdc.gov/std/treatment/2010/hepc.htm

Infants born to mothers with HCV

Infants born to HCV-positive mothers should be tested for HCV infection. Children born to HCV-positive mothers can be tested with the HCV RNA tests at 2 months of age or older (at a routine well-child visit), or HCV antibody testing can be done at 18 months of age (HCV antibody testing should be delayed until 18 months of age to avoid detecting maternal antibody).

The Kentucky Department for Public Health recommends the use of quantitative HCV RNA tests at 2 months of age or older to assess whether HCV was transmitted to the infant from the HCV-positive mother.

http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm

Complete and fax the reporting form at the end of this newsletter.

Fax forms to 502-696-3803



Perinatal Hepatitis B:

Hepatitis B virus (HBV) infection in a pregnant woman poses a serious risk to her infant at birth. Without post-exposure immune prophylaxis, approximately 40% of infants born to HBV-infected mothers in the United States will develop chronic HBV infection, approximately one-fourth of whom will eventually die from chronic liver disease.

Perinatal HBV transmission can be prevented by identifying HBV-infected (i.e., Hepatitis B surface antigen [HBsAg]-positive) pregnant women and providing Hepatitis B immune globulin and Hepatitis B vaccine to their infants within 12 hours of birth.

Preventing perinatal HBV transmission is an integral part of the national strategy to eliminate Hepatitis B in the United States. National guidelines call for the following:

- Universal screening of pregnant women for HBsAg during each pregnancy
- Case management of HBsAg-positive mothers and their infants
- Provision of immunoprophylaxis for infants born to infected mothers, including Hepatitis B vaccine and Hepatitis B immune globulin
- Routine vaccination of all infants with the Hepatitis B vaccine series, with the first dose administered
 at birth

Guidelines and Recommendations

Hepatitis B Vaccination Recommendations for Infants, Children, and Adolescents MMWR 2005;54(RR-16)

Main Document(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e)

Appendix A(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a2.htm?s_cid=rr5416a2_e)

Case Finding and Management of HBsAg-Positive Persons

<u>Appendix B(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a3.htm?s_cid=rr5416a3_e)</u> Immunization Management Issues

<u>Appendix C(http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a4.htm?s_cid=rr5416a4_e)</u>
Post-exposure Prophylaxis

<u>PDF version[PDF - 39 pages](http://www.cdc.gov/migration/iteration3.1/mmwr/pdf/rr/rr5416.pdf)</u> (with appendices)





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